

MANAGEMENT OF RADIOACTIVE MATERIALS

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) Directive establishes policy necessary to implement the requirements of the VHA Master Materials License (MML) issued by the Nuclear Regulatory Commission (NRC). **NOTE:** *This directive does not apply to the licensing and operation of the nuclear reactor facility at the Department of Veterans Affairs (VA) Medical Center, Omaha, NE.*

2. SUMMARY OF MAJOR CHANGES: This is a new VHA Directive that describes the structure and role of the MML oversight program, including the VHA National Radiation Safety Committee (NRSC) and the VHA National Health Physics Program (NHPP).

3. RELATED ISSUES: VHA Handbook 1105.1.

4. RESPONSIBLE OFFICE: The Chief Patient Care Services Officer (11) is responsible for the contents of this VHA Handbook. Questions may be referred to the Director, NHPP at (501) 257-1571.

5. RESCISSIONS: None.

6. RECERTIFICATION: This document will be recertified on or before the last working day of March 2005.

S/ by Frances Murphy, M.D. for
Thomas L. Garthwaite, M.D.
Deputy Under Secretary for Health

Distribution: **RPC: 0005**
FD

Printing Date: 3/2000

MANAGEMENT OF BYPRODUCT RADIOACTIVE MATERIAL IN THE VHA

1. PURPOSE: This Veterans Health Administration (VHA) Directive defines policy for implementing and establishing the Master Materials License (MML) structure and operations prior to issuance of the MML. When the MML is issued, a VHA byproduct material permit or permits will be issued to each facility to replace its individual United States Nuclear Regulatory Commission (NRC) license(s).

2. BACKGROUND

a. The use of radioactive material produced using nuclear fission, called byproduct material, is regulated by the NRC. The VHA has applied for a single NRC license, called an MML, to replace the individual NRC licenses held by many VHA medical facilities.

b. The VHA National Radiation Safety Committee (NRSC) and National Health Physics Program (NHPP) are directed to perform regulatory activities regarding the use of byproduct material at VHA facilities. The issuance of VHA byproduct material permits to replace the NRC licenses currently held by individual VA facilities is not to occur until the NRC has issued the MML to the VHA. ***NOTE:** This directive does not apply to the licensing and operation of the nuclear reactor facility at the Department of Veterans Affairs (VA) Medical Center, Omaha, NE.*

3. POLICY

a. **Routing of Correspondence from Facilities to the NRC.** Effective immediately, facilities are instructed to route NRC license applications, requests for license amendments, and other licensing communications with the NRC through the NHPP at the following address. Facilities should not contact the NRC directly, as the NHPP will promptly forward the information to the NRC.

National Health Physics Program (115HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
North Little Rock, AR 72114

b. **Review of NRC License Applications, Amendment Requests, and Other Correspondence.** The NHPP is directed to review all facility correspondence with the NRC prior to forwarding it to the NRC. The NHPP may request additional information from the facilities before forwarding the correspondence.

c. **Notification of Incidents.**

(1) Facilities shall notify the NHPP of incidents involving radioactive materials, including medical misadministrations, when notification of the NRC is required under Title 10 Code of Federal Regulations (CFR) Parts 20, 21, 30, or 35. All reports required by NRC regulations

following incidents shall be submitted through the NHPP. The NHPP will communicate with the NRC as necessary. **NOTE:** *This does not mean that safety concerns and other protected activities (see VA Manual MP-3, Part 3; 29 CFR Part 1960 (OSHA); 10 CFR Parts 19 and 30 (Energy); the Civil Service Reform Act of 1978 (CSRA); and the Whistleblower Protection Act of 1989 (WPA) (Public Law 101-12)) cannot be communicated directly to the outside agency.*

(2) Notifications shall be made and reports shall be submitted to the NHPP within the time frames required by VHA Handbook 1105.1.

d. **Notification of NRC Inspections.** Facilities shall also notify the NHPP when the NRC performs an inspection.

e. **Assistance with Incidents.** Facilities are encouraged to contact the NHPP at the earliest possible time for assistance or if further information is needed.

f. **Inspections by NHPP.** The NHPP will perform inspections of Department of Veterans Affairs (VA) medical facilities holding NRC licenses. Initial inspections of new facilities and inspections in reaction to incidents will usually be announced in advance. However, routine inspections will be conducted without prior notification. The frequency of inspections is described in VHA Handbook 1105.1. The intervals between inspections will be extended for good performance when there have not been significant program changes. The inspection intervals may be reduced for poor performance. An inspection report will be sent to the facility with a copy to the Veterans Integrated Service Network (VISN) following each inspection.

g. **Notices of Violations.** When violations of NRC regulations or NRC license conditions are found during an inspection, the inspected facility will be sent a Notice of Violation (NOV) describing the violations. Each violation or group of similar violations will be assigned a Severity Level. Each facility receiving a NOV will be required to respond in writing within 30 days.

h. **Enforcement Actions.** Enforcement actions shall be used as a deterrent to emphasize the importance of compliance with MML requirements and to encourage prompt identification and comprehensive correction of items of regulatory non-compliance. The NRSC's role in the enforcement process is to review and sanction all enforcement actions. The NHPP will immediately report any violations categorized at a Severity Level I, II, or III to the NRSC and the NRC as required under the MML. **NOTE:** *Under the MML, the NRC retains the right to implement escalated enforcement actions and issue orders concerning MML regulated activities. The NRC also reserves the right to impose civil penalties in accordance with NRC's Enforcement Policy.*

3. ACTION: The following responsibilities are authorized:

a. **The Under Secretary for Health.** The Under Secretary establishes and promulgates VHA policy for control of ionizing radiation uses and hazards and is the responsible official for the MML Program.

b. **VHA NRSC**. The NRSC is the principal organizational element for implementation of the MML and, as such:

- (1) Provides guidance and information on the radiation control program to the Under Secretary.
- (2) Informs the Under Secretary of the resources needed to maintain an adequate radiation control program.
- (3) Oversees activities of the NHPP in the development, implementation, and maintenance of a radiation control program.
- (4) Establishes and maintains administrative operations regulation of acquisition, receipt, storage, distribution, use, transfer, and disposal of radioactive materials.
- (5) Initiates program policy and enforcement actions as delegated to the NRSC by the Under Secretary for Health.
- (6) Reviews and enforces or modifies, as appropriate, actions of the NHPP Office.
- (7) Reviews and assesses NHPP permitting and inspection staff to assure that the qualifications described in NRC Inspection Manual Chapter 1246 are met or exceeded.
- (8) Promulgates policy and procedures for implementation by the NHPP office staff.
- (9) Reviews staff actions and NRC license amendment requests or permit applications referred by the NHPP Office.
- (10) Advises the Under Secretary of non-compliance categorized at Severity Levels I, II, and III, as identified in NRC enforcement policy, and of the results of NRSC audits and program reviews.
- (11) Arranges for, reviews, and participates with independent safety experts, as necessary, in an annual review and audit of the radiation safety program for regulatory compliance and specifies corrective actions, as necessary. Enforces, consistent with the NRC-allowed or – delegated regulatory authority and license conditions, all terms, conditions, and commitments contained in existing NRC licenses and, after an agreement with the NRC, the MML and its application, as defined by MML enforcement procedures.
- (12) Meets, as necessary, at the call of the Chairperson, but not less than once in each quarter.

c. **Director, NHPP**. The Director, NHPP, serves as the principal radiation safety specialist for the VHA; is responsible for administration of the VHA MML Program, and:

- (1) Serves as the Executive Secretary of the NRSC.

- (2) Supervises NHPP field personnel performing facility inspections and reviews of NRC license applications and amendment requests.
- (3) Maintains records required by regulatory agencies and, as otherwise necessary, for implementation of the VHA radiation control program.
- (4) Initiates procedures to implement policy and program requirements established by the Under Secretary for Health, NRSC, or the NRC.
- (5) Implements the NRSC's enforcement actions.
- (6) Implements the NRC's enforcement actions.
- (7) Stops, in coordination with NHPP field personnel, work activities that may pose undue risk or hazard or that violate conditions of NRC licenses or regulations.
- (8) Reviews all radiological incidents and accidents to ensure safety and compliance with applicable rules and regulations and recommends corrective action to the NRSC.

d. **VISN Directors.** The VISN Directors serve as liaison between the NRSC and facilities within their network through monitoring and oversight by the Chief Network Officer (CNO) representative on the NRSC. VISNs will be provided a copy of all relevant correspondence between the facility, the NRSC and the NHPP.

e. **Medical Facility Directors.** The medical facilities Directors are designated as responsible officials for oversight of the facilities' radiation protection programs. They are responsible for assuring that sufficient staff and resources are available for proper conduct of the program and that relevant committees, as required by the MML, are performing properly.

4. REFERENCES

- a. United States (U.S.) Nuclear Regulatory Commission, Title 10 CFR Parts 19, 20, 30-33, 35, and 71.
- b. U.S. Department of Transportation, Title 49 CFR Parts 100 to 177, "Transportation."